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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,401	03/22/2001	Mark D. Einziger	1932/0H835	3826

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EXAMINER

EVANS, CHARESSE L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,401

Applicant(s)

EINZIGER ET AL.

Examiner

Charess L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-16 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-16 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Action Summary

Acknowledgement s made of the receipt of change of correspondence address, amendment and remarks, filed April 30, 2003.

The rejection of record of claim 3, under 35 USC 112, second paragraph, is withdrawn.

The rejection of record of claims 3-13 and 24 under 35 USC 103(a) over Masters et al (US 5,855,871) is maintained.

The rejection of record of claims 14-16 and 23-25, under 35 USC 103(a) over Masters et al in view of Itob (US 5,071,558), is maintained.

Claims 3-16 and 23-25 are active in this action.

Response to Arguments

Applicant's arguments filed April 30, 2003, have been fully considered but they are not persuasive. Applicant argues that the claimed invention differs from the cited prior art, which contained no more than about 15% of weight of bicarbonate in a non-aqueous suspension. What is the criticality of using the claimed amount of bicarbonate at 50%-80%? What are the unexpected results obtained by using this

amount? Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). It is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations.

However, absent a clear showing of criticality, the determination of the particular ranges and administration regiment is within the skill of the ordinary worker as part of the process of normal optimization. The courts have held the “concentration limitations are obvious absent a showing of criticality.” Azko v. E.E. Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

Regarding applicant’s arguments that Itob achieves the particle shape and size via conventional granulating procedures rather than by grinding, is not persuasive. That indeed may be the case, however, applicant’s claims are to a composition and not to a method. In a composition, patentable weight is not given to the reason for including a component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and

advantages are inherent to the composition. Therefore, the fact that applicants argue that their particle sizes can be achieved by grinding, rather than by conventional granulation procedures, has no patentable weight.

The rejection is maintained.

The previous rejection has been restated following the conclusion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masters et al (US 5,855,871). The elected claims are directed to a slurry comprising spherically shaped and micron sized alkali metal bicarbonate particles in a liquid medium. Masters discloses a composition containing an alkali metal bicarbonate incorporated within a pharmaceutically acceptable dentifrice vehicle suitable for use in the oral cavity. The vehicle contains water and other agents

(column 2, lines 39-59). The water content is from about 30% to about 60% (column 3, lines 1-2). The alkali metal bicarbonate contained in the disclosed composition is present from about 5 up to 15% by weight (column 3, lines 5-7). The alkali metal bicarbonate present within the composition includes sodium bicarbonate. Sodium bicarbonate is a powder composed of relatively soft particles (column 3, lines 21-24). The size of the sodium bicarbonate particles may vary from course to fine; it is preferred that they be below about 0.4mm in diameter, with a major proportion being below 0.01mm in diameter. The vehicle in which the sodium bicarbonate particles are dispersed is an aqueous vehicle (column 3, lines 20-31). Common ingredients with the disclosed composition include polishing agents, abrasives, surfactants, humectants, pigments, sweeteners, flavor and preservatives (columns 4-5, to line 60).

The prior art does not expressly teach the bulk density, the viscosity or the IR spectra of the bicarbonate particles. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are structurally or functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303

(PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 14-16 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masters et al (US (5,855,871) in view of Itob (US 5,071,558). In light of the discussion above, Itob further discloses a sodium bicarbonate dialysate. The dialytic solution is used to remove uremic waste by means of hemodialysis. The disclosed invention provides a sodium bicarbonate dialysate comprising an electrolyte granule A and an electrolyte granule B, wherein the granule B are granules of sodium bicarbonate primary particles having a particle size of at most 250 micrometers, and the particle size of the secondary particles after granulation is from 0.1 to 10 mm (column 1, lines 8-68). It is preferred that the particle size of the sodium bicarbonate primary particles is at most 100, more preferred at most 50, micrometers (column 2, lines 14-17). The granule B may contain sodium bicarbonate only or may further contain other electrolytes. Other components may optionally be incorporated (column 2, lines 31-33).

When the granules of the referenced invention are to be granulated, powders of the respective components are mixed together with a suitable amount of water. The examples, in columns 6-8, demonstrate a preparation of a solution of the granule B, wherein granule B was placed in water and stirred by magnetic stirrer. Additionally, an amount of granule B along with an amount of granule A were dissolved in water at

25 degrees Celsius and then adjusted to over 2 liters (column 6, lines 28-31). When being utilized as a dialytic solution, the bicarbonate dialysate was dissolved in a volume of water (column 9, lines 17-18).

One would be motivated to combine the teachings of the cited references because utilizing granulated or particulate bicarbonate dialysates are useful as waste or debris removal solutions in a variety of compositions. The expected result would be optimization of the easy solubility of bicarbonate dialysates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday -Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1300